

## **Remarks**

Claims 1-3, 7, 8, 10-32, 36, 37, 42-45, and 75 are pending in the above-referenced application before entrance of the present Amendment. The Examiner has rejected all the pending claims. Claims 1-3 are amended in this Response; and claims 7, 8, 13, and 14 have been canceled. No new claims have been added. Support for the amendments to claims 1-3 can be found in original claim 8. Applicant respectfully submits that no new matter is presented with these amendments. Applicant reserves the right to prosecute without prejudice in a future application subject matter amended from the claims by the Amendment submitted herewith. Applicant respectfully requests consideration of the amended claims presented herein and respectfully submits that the amended claims are now in condition for allowance.

**Rejection under 35 U.S.C. § 112, first paragraph.** The Examiner has rejected claims 1-3, 7, 8, 10-29, 42-45, and 75 under § 112, first paragraph, for lack of enablement. The Examiner maintains that the Applicant's disclosure is not enabled because the Applicant has not demonstrated success with the inventive system for therapeutic use. In particular, the Examiner notes that the "Applicants' success in the model system noted does not lead to a conclusion of enablement for the claimed invention." Applicant disagrees and respectfully submits that the Examiner has improperly read a therapeutic use limitation into the claims. The amended claims are fully supported under § 112 by the originally filed specification.

In regard to the method claims (claims 1-3, 10-12, 15-29, and 75), these claims do not recite any type of therapeutic use. Applicant submits that the Examiner is improperly reading a limitation into the claims. MPEP § 2111, citing *In re Prater*, 162 USPQ 541, 550 (CCPA 1969) ("‘reading a claim in the light of the specification,’ to thereby interpret limitations explicitly recited in the claim, is quite a different thing from ‘reading limitations of the specification into a claim,’ to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim"). The claimed methods are not only useful for therapeutic purposes but are also useful for research purposes. The "Background of the Invention" section of the present application points out that stem cells are important in research. See page 2, line 16, of the originally filed specification. This section goes on to point out how difficult it is to expand populations of stem cells without loss of their multipotentiality. Therefore, the Examiner

is wrong to maintain that the claimed methods are only useful for therapeutic purposes. They are also useful for research purposes, and the Examples, particularly Example 3 (starting on page 44, line 21), clearly demonstrate that inhibiting p21 in stem cells results in expansion of stem cell populations. Given this working example, Applicant submits that the claimed methods are fully enabled by the application as originally filed. Applicant respectfully requests that the rejection of these claims be removed.

The claims to cells “with less than wild type p21 activity” are also fully enabled by the specification. Both working Examples 1 and 3 demonstrate cells with less than wild type p21 activity. Therefore, Applicant has clearly shown that such claims are enabled. The Examiner has provided no evidence to support his argument that such claims are not enabled. Even if Applicant agrees with the Examiner for argument sake that such cells are not suitable for therapeutic use, they are still useful for research purposes. Applicant respectfully requests that these claims be allowed.

Finally, with respect to the rejected claims drawn to pharmaceutical compositions (claims 42-45) of hematopoietic cells with less than wild type p21 activity, Applicant submits that these claims are enabled by the specification as further supported by the Declaration of Scadden, submitted June 22, 2005. As previously pointed out by the Applicant, the inventive pharmaceutical compositions are particularly useful in bone marrow transplantation in the treatment of hematological malignancies. As demonstrated in Example 3 of the specification, hematopoietic cells with less than wild type p21 activity have been found to successfully repopulate the bone marrow of irradiated animals. The Examiner has provided no evidence to show that such cells could not be used in repopulating the bone marrow of a bone marrow transplant patient. Applicant submits that the claims drawn to pharmaceutical compositions of hematopoietic cells with less than wild type p21 activity are enabled.

The claims are fully enabled by the specification. Applicant respectfully requests that the rejection for lack of enablement be removed. The pending claims are now in condition for allowance.

If it is believed that a telephone conversation would expedite matters, the Examiner is invited to contact the undersigned at (617) 248-5215. Although it is believed that there is no fee

associated with this amendment, if Applicant is mistaken, please charge any fees to our Deposit  
Account Number: 03-1721.

Respectfully submitted,



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